



## Summary Table of FDA Authorized COVID-19 Tests For In Vitro Diagnostics from Test Kit Manufacturers and Commercial Laboratories

This information is current and accurate as of **June 1, 2020**. This document will be updated on a weekly basis, if needed. For the most current information on COVID-19 tests with Emergency Use Authorization (EUA), visit the FDA website:

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

The California Pharmacists Association (CPhA) does not endorse the use of any specific product or manufacturer. Lists are organized alphabetically by manufacturer.

### Abbreviations:

N: Nasal (nasopharyngeal, nasal, anterior nasal, and mid-turbinate nasal swab)

O: Oral (oropharyngeal or throat swab)

RS: Respiratory Specimens (bronchoalveolar lavage, tracheal aspirate, or nasal wash/aspirate)

SP: Sputum

S: Saliva

B: Blood specimens (serum, plasma, or whole blood)

FS: Fingerstick

HC: High complexity test

MC: Moderate complexity test

W/PCS: Waived/Patient care settings (i.e., settings with CLIA Certificate of Waiver or Certificate of Compliance)

H: At home self-collection

### Summary:

Number of authorized laboratory developed tests (LDT): 32

Number of authorized molecular diagnostics: 70

Number of authorized serological diagnostics: 15

Number of tests authorized for CLIA-waived settings: 4

Number of labs authorized for at home self-collection: 6

Number of home collection test kits: 1



**Antigen Diagnostic - detecting fragments of viral proteins**

CLIA-Waived Tests.

| Test                     | Manufacturer       | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|--------------------------|--------------------|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|                          |                    | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| Sofia 2 SARS Antigen FIA | Quidel Corporation | ✓        |   |    |    |   |   | ✓                    | ✓  | ✓ |   | 5/8/2020    |

**Molecular Diagnostic - detecting nucleic acid**

Home Collection Kit.

| Test             | Manufacturer                                 | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|------------------|--|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|                  |  | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| Everlywell, Inc. | Everlywell COVID-19 Test Home Collection Kit | ✓        |   |    |    |   |   |                      |    |   | ✓ | 5/15/20     |

\*Other laboratory-based tests with home collection options listed in the table on the following pages

CLIA-Waived Tests.

| Test                         | Manufacturer                         | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|------------------------------|--------------------------------------|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|                              |                                      | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| ID NOW COVID-19              | Abbott Diagnostics Scarborough, Inc. | ✓        | ✓ |    |    |   |   | ✓                    | ✓  | ✓ |   | 3/27/20     |
| Xpert Xpress SARS-CoV-2 test | Cepheid                              | ✓        |   | ✓  |    |   |   | ✓                    | ✓  | ✓ |   | 3/20/20     |
| Accula SARS-Cov-2 Test       | Mesa Biotech Inc.                    | ✓        | ✓ |    |    |   |   | ✓                    | ✓  | ✓ |   | 3/23/20     |



Not CLIA-Waived Tests.

| Test  | Manufacturer                      | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |         |
|---|-----------------------------------|----------|---|----|----|---|---|----------------------|----|---|---|-------------|---------|
|   |                                   | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |         |
| GeneFinder COVID-19 Plus RealAmp Kit        | OSANG Healthcare                  | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 4/18/20 |
| 1copy COVID-19 qPCR Multi Kit               | 1drop Inc.                        | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 5/11/20 |
| Abbot RealTime SARS-CoV-2 assay             | Abbott Molecular                  | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/18/20 |
| Alinity m SARS-CoV-2 assay                  | Abbott Molecular Inc.             | ✓        | ✓ | ✓  |    |   |   | ✓                    | ✓  |   |   |             | 5/11/20 |
| RealStar SARS-CoV2 RT-PCR Kits U.S.         | altona Diagnostics GmbH           | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 4/22/20 |
| Linea COVID-19 Assay Kit                    | Applied DNA Sciences, Inc.        | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 5/13/20 |
| Assurance SARS-CoV-2 Panel                  | Assurance Scientific Laboratories | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   | ✓           | 5/15/20 |
| iAMP COVID-19 Detection Kit                 | Atila BioSystems, Inc.            | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 4/10/20 |
| AvellinoCoV2 test                           | Avellino Lab USA, Inc.            | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/25/20 |
| BD SARS-CoV-2 Reagents for BD MAX System    | Becton, Dickinson & Company       | ✓        | ✓ |    |    |   |   | ✓                    | ✓  |   |   |             | 4/8/20  |
| BioGX SARS-CoV-2 Reagents for BD MAX System | Becton, Dickinson & Company (BD)  | ✓        | ✓ |    |    |   |   | ✓                    | ✓  |   |   |             | 4/2/20  |



Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test  | Manufacturer              | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|---|---------------------------|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|   |                           | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV                 | BGI Genomics Co. Ltd      |          | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 3/26/20     |
| Bio-Rad SARS-CoV-2 ddPCR Test   | Bio-Rad Laboratories, Inc | ✓        |   | ✓  |    |   |   | ✓                    |    |   |   | 5/1/20      |
| BioCore 2019-nCoV Real Time PCR Kit   | BioCore Co., Ltd.         | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 5/21/20     |
| BioFire COVID-19 Test   | BioFire Defense, LLC      | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   | 3/23/20     |
| BioFire Respiratory Panel 2.1 (RP2.1)   | BioFire Diagnostics, LLC  | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   | 5/1/20      |
| SARS-COV-2 R-GENE   | BioMérieux SA             | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 5/6/20      |
| CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel (CDC)                         | CDC                       | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 2/4/20      |
| New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel | CDC                       | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 2/29/20     |
| Logix Smart Coronavirus Disease 2019 (COVID-19) Kit                           | Co-Diagnostics, Inc.      | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 4/3/20      |
| Hymon SARS-CoV-2 Test Kit   | dba SpectronRx            | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 5/22/20     |



| Test   | Manufacturer  | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |         |
|--|---|----------|---|----|----|---|---|----------------------|----|---|---|-------------|---------|
|  |   | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |         |
| QuantiVirus SARS-CoV-2 Test kit                | DiaCarta, Inc   | ✓        | ✓ |    | ✓  |   |   | ✓                    |    |   |   |             | 4/8/20  |
| Simplexa COVID-19 Direct assay                 | DiaSorin Molecular LLC  | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   |             | 3/19/20 |
| FTD SARS-CoV-2                                 | Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company) | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 5/5/20  |
| Fosun COVID-19 RT-PCR Detection Kit            | Fosun Pharma USA Inc.   | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 4/17/20 |
| Fulgent COVID-19 by RT-PCR Test                | Fulgent Therapeutics, LLC   | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   | ✓           | 5/15/20 |
| NeoPlex COVID-19 Detection Kit                 | GeneMatrix, Inc.  | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 5/14/20 |
| ePlex SARS-CoV-2 Test                          | GenMark Diagnostics, Inc.   | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   |             | 3/19/20 |
| GS™ COVID-19 RT-PCR KIT                        | GenoSensor, LLC   | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 4/16/20 |
| Gnomegen COVID-19 RT-Digital PCR Detection Kit | Gnomegen LLC  | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 4/6/20  |
| Gnomegen COVID-19-RT-qPCR Detection Kit        | Gnomegen LLC  | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 5/8/20  |
| Aptima SARS-CoV-2 assay                        | Hologic, Inc.   | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 5/14/20 |



Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test                                | Manufacturer                                | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |         |
|-------------------------------------|---|----------|---|----|----|---|---|----------------------|----|---|---|-------------|---------|
|                                     |   | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |         |
| Panther FUSion SARS-CoV-2           | Hologic, Inc.                               | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/16/20 |
| Smart Detect SARS-CoV-2 rRT-PCR Kit | InBios International, Inc                   | ✓        |   |    |    |   |   | ✓                    |    |   |   |             | 4/7/20  |
| COV-19 IDx Assay                    | Ipsium Diagnostics, LLC                     | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 4/1/20  |
| Curative-Korva SARS-Cov-2 Assay     | KorvaLabs Inc.                              | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 4/16/20 |
| LabGun COVID-19 RT-PCR Kit          | LabGenomics Co., Ltd.                       | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 4/29/20 |
| COVID-19 RT-PCR Test                | Laboratory Corporation of America (LabCorp) | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | ✓           | 3/16/20 |
| ARIES SARS-CoV-2 Assay              | Luminex Corporation                         | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   |             | 4/3/20  |
| NxTAG CoV Extended Panel Assay      | Luminex Molecular Diagnostics, Inc.         | ✓        |   |    |    |   |   | ✓                    |    |   |   |             | 3/27/20 |
| SARS-CoV-2 Fluorescent PCR Kit      | Maccura Biotechnology (USA) LLC             | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 4/15/20 |
| NeuMoDx SARS-CoV-2 Assay            | NeuMoDx Molecular, Inc.                     | ✓        | ✓ |    |    |   |   | ✓                    | ✓  |   |   |             | 3/30/20 |
| OPTI SARS-CoV-2 RT PCR Test         | OPTI Medical Systems, Inc.                  | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 5/6/20  |
| P23 Labs TaqPath SARS-CoV-2 Assay   | P23 Labs, LLC.                              | ✓        | ✓ | ✓  |    | ✓ |   | ✓                    |    |   |   | ✓           | 5/21/20 |



Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test   | Manufacturer                               | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |         |
|--|--|----------|---|----|----|---|---|----------------------|----|---|---|-------------|---------|
|  |  | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |         |
| PerkinElmer New Coronavirus Nucleic Acid Detection Kit | PerkinElmer, Inc                           | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/24/20 |
| Primerdesign Ltd COVID-19 genesig Real-Time PCR assay  | Primerdesign Ltd.                          |          | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/20/20 |
| LetsGetChecked Coronavirus (COVID-19) Test             | PrivaPath Diagnostics, Inc.                | ✓        |   |    |    |   |   | ✓                    |    |   |   | ✓           | 5/28/20 |
| QIAstat-Dx Respiratory SARS-CoV-2 Panel                | QIAGEN GmbH                                | ✓        |   |    |    |   |   | ✓                    | ✓  |   |   |             | 3/30/20 |
| Quest SARS-CoV-2 rRT-PCR                               | Quest Diagnostics Infectious Disease, Inc. | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   |             | 3/17/20 |
| Lyra SARS-CoV-2 Assay                                  | Quidel Corporation                         | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/17/20 |
| Lyra Direct SARS-CoV-2 Assay                           | Quidel Corporation                         | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 5/18/20 |
| Rheonix COVID-19 MDx Assay                             | Rheonix, Inc.                              | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   |             | 4/29/20 |
| cobas SARS-CoV-2                                       | Roche Molecular Systems, Inc. (RMS)        | ✓        | ✓ |    |    |   |   | ✓                    |    |   |   |             | 3/12/20 |



Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test   | Manufacturer  | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|--|---|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|  |   | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2-Assay                        | Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics - Rutgers University | ✓        | ✓ | ✓  |    | ✓ |   | ✓                    |    |   | ✓ | 5/7/20      |
| Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | Sansure BioTech Inc.  | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 5/4/20      |
| ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit            | ScienCell Research Laboratories   | ✓        |   | ✓  |    |   |   | ✓                    |    |   |   | 4/3/20      |
| STANDARD M nCoV Real-Time Detection Kit  | SD Biosensor, Inc.  | ✓        | ✓ |    | ✓  |   |   | ✓                    |    |   |   | 4/23/20     |
| U-TOP COVID-19 Detection Kit   | SEASUN BIOMATERIALS   | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 4/27/20     |
| AQ-TOP COVID-19 Rapid Detection Kit  | Seasun Biomaterials, Inc.   | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 5/21/20     |
| Allplex 2019-nCoV Assay  | Seegene, Inc.   | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 4/21/20     |
| Sherlock CRISPR SARS-CoV-2 Kit   | Sherlock BioSciences, Inc.  | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 5/6/20      |





Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test   | Manufacturer                   | Specimen |   |    |    |   |   | Authorized Locations |    |   |   | Date Issued |
|--|--------------------------------|----------|---|----|----|---|---|----------------------|----|---|---|-------------|
|  |                                | N        | O | RS | SP | S | B | HC                   | MC | W | H |             |
| DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit | SolGent Co., Ltd.              | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 5/21/20     |
| TaqPath COVID-19 Combo Kit                           | Thermo Fisher Scientific, Inc. | ✓        |   | ✓  |    |   |   | ✓                    |    |   |   | 3/13/20     |
| PhoenixDx 2019-CoV                                   | Trax Management Services Inc.  | ✓        | ✓ | ✓  |    |   |   | ✓                    |    |   |   | 4/20/20     |
| Quick SARS-CoV-2rRT-PCR Kit                          | Zymo Research Corporation      | ✓        | ✓ | ✓  | ✓  |   |   | ✓                    |    |   |   | 5/7/20      |



**Serological Diagnostic - detecting antibodies**

Currently none are CLIA-waived.

**Total Antibody**

| Test  | Manufacturer  | Specimen |    | Authorized Locations |    |   |   | Date Issued |
|---|---|----------|----|----------------------|----|---|---|-------------|
|   |   | B        | FS | HC                   | MC | W | H |             |
| Platelia SARS-CoV-2 Total Ab assay                                  | Bio-Rad Laboratories, Inc                             | ✓        |    | ✓                    |    |   |   | 4/29/20     |
| VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack | Ortho Clinical Diagnostics, Inc.                      | ✓        |    | ✓                    | ✓  |   |   | 4/14/20     |
| Elecsys Anti-SARS-CoV-2   | Roche Diagnostics                                     | ✓        |    | ✓                    | ✓  |   |   | 5/2/20      |
| Atellica IM SARS-CoV-2 Total (COV2T)                                | Siemens Healthcare Diagnostics Inc.                   | ✓        |    | ✓                    | ✓  |   |   | 5/29/20     |
| ADVIA Centaur SARS-CoV-2 Total (COV2T)                              | Siemens Healthcare Diagnostics Inc.                   | ✓        |    | ✓                    | ✓  |   |   | 5/29/20     |
| New York SARS-CoV Microsphere Immunoassay for Antibody Detection    | Wadsworth Center, New York State Department of Health | ✓        |    | ✓                    |    |   |   | 4/30/20     |



IgG and IgM

| Test  | Manufacturer                   | Specimen |    | Authorized Locations |    |   |   | Date Issued |
|---|--------------------------------|----------|----|----------------------|----|---|---|-------------|
|   |                                | B        | FS | HC                   | MC | W | H |             |
| Anti-SARS-CoV-2 Rapid Test                                      | Autobio Diagnostics Co. Ltd.   | ✓        |    | ✓                    | ✓  |   |   | 4/24/20     |
| qSARS-CoV-2 IgG/IgM Rapid Test                                  | Cellex Inc.                    | ✓        |    | ✓                    | ✓  |   |   | 4/1/20      |
| DPP COVID-19 IgM/IgG System                                     | ChemBio Diagnostic System, Inc | ✓        | ✓  | ✓                    | ✓  |   |   | 4/14/20     |
| COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) | Healgen Scientific LLC         | ✓        |    | ✓                    | ✓  |   |   | 5/29/20     |

IgG only

| Test  | Manufacturer                     | Specimen |    | Authorized Locations |    |   |   | Date Issued |
|---|----------------------------------|----------|----|----------------------|----|---|---|-------------|
|   |                                  | B        | FS | HC                   | MC | W | H |             |
| SARS-CoV-2 IgG assay  | Abbott Laboratories Inc.         | ✓        |    | ✓                    | ✓  |   |   | 4/26/20     |
| LIAISON SARS-CoV-2 S1/S2 IgG                                      | DiaSorin Inc.                    | ✓        |    | ✓                    | ✓  |   |   | 4/24/20     |
| Anti-SARS-CoV-2 ELISA (IgG)                                       | EUROIMMUN US Inc.                | ✓        |    | ✓                    |    |   |   | 5/4/20      |
| COVID-19 ELISA IgG Antibody Test                                  | Mount Sinai Laboratory           | ✓        |    | ✓                    |    |   |   | 4/15/20     |
| VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack | Ortho-Clinical Diagnostics, Inc. | ✓        |    | ✓                    | ✓  |   |   | 4/24/20     |



## Summary Table of FDA Authorized COVID-19 Tests For High Complexity Molecular-Based Laboratory Developed Tests

\*Authorized for use in the single laboratory that developed the authorized test

| Test  | Laboratory   | Specimen |   |    |    |   |   | Date Issued |
|---|--|----------|---|----|----|---|---|-------------|
|   |  | N        | O | RS | SP | S | B |             |
| SARS-CoV-2 Assay                                    | AIT Laboratories   | ✓        | ✓ | ✓  | ✓  |   |   | 4/24/20     |
| Altru Dx SARS-CoV-2 RT-PCR assay                    | Altru Diagnostics, Inc.  | ✓        | ✓ |    |    |   |   | 4/30/20     |
| Avera Institute for Human Genetics SARS-CoV-2 Assay | Avera Institute for Human Genetics   | ✓        | ✓ | ✓  |    |   |   | 5/22/20     |
| SARS-CoV-2 Test                                     | Biocerna   | ✓        | ✓ | ✓  |    |   |   | 4/28/20     |
| Biocollections Worldwide SARS-Co-V-2 Assay          | Biocollections Worldwide, Inc.   | ✓        | ✓ | ✓  |    |   |   | 5/7/20      |
| SARS-CoV-2-Assay                                    | Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine | ✓        |   |    |    |   |   | 5/13/20     |
| CirrusDx SARS-CoV-2 Assay                           | CirrusDx Laboratories  | ✓        | ✓ | ✓  |    |   |   | 4/15/20     |
| Triplex CII-CoV-1 rRT-PCR Test                      | Columbia University Laboratory of Personalized Genomic Medicine              | ✓        | ✓ | ✓  |    |   |   | 5/12/20     |
| SARS-Cov-2 Assay                                    | Diagnostic Molecular Laboratory - Northwestern Medicine                      | ✓        | ✓ | ✓  |    |   |   | 4/2/20      |
| SARS-CoV-2 PCR Test                                 | Diatherix Eurofins Laboratory  | ✓        | ✓ | ✓  | ✓  |   |   | 4/22/20     |
| SARS-CoV-2 Test                                     | Exact Sciences Laboratories  | ✓        | ✓ |    |    |   |   | 4/14/20     |
| Exact Sciences SARS-CoV-2 (N gene detection) Test   | Exact Sciences Laboratories  | ✓        | ✓ |    |    |   |   | 5/22/20     |
| Express Gene 2019-nCoV RT-PCR Diagnostic Panel      | Express Gene LLC (dba Molecular Diagnostics Laboratory)                      | ✓        | ✓ | ✓  |    |   |   | 5/22/20     |



Summary Table of COVID-19 Tests  
Last updated June 1, 2020

| Test  | Laboratory  | Specimen |   |    |    |   |   | Date Issued |
|---|---|----------|---|----|----|---|---|-------------|
|   |   | N        | O | RS | SP | S | B |             |
| CDI Enhanced COVID-19 Test                    | Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory      | ✓        | ✓ | ✓  |    |   |   | 4/15/20     |
| SARS-CoV-2 RT-PCR test                        | Infectious Disease Diagnostics Laboratory - Children's Hospital of Philadelphia | ✓        |   | ✓  |    |   |   | 4/2/20      |
| Childrens-Altona-SARS-CoV-2 Assay             | Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children's Hospital   | ✓        | ✓ |    |    |   |   | 4/14/20     |
| SARS-CoV-2 Assay                              | Integrity Laboratories  | ✓        | ✓ |    |    |   |   | 4/13/20     |
| MGH COVID-19 qPCR assay                       | Massachusetts General Hospital  | ✓        | ✓ | ✓  |    |   |   | 4/3/20      |
| SARS-CoV-2 Molecular Detection Assay          | Mayo Clinic Laboratories, Rochester, MN   | ✓        | ✓ | ✓  | ✓  |   |   | 4/20/20     |
| SARS-CoV-2 Assay                              | Nationwide Children's Hospital  | ✓        | ✓ | ✓  | ✓  |   |   | 4/27/20     |
| SARS-CoV-2 Real-Time RT-PCR-Test              | One Health Laboratories, LLC  | ✓        | ✓ | ✓  |    |   |   | 5/13/20     |
| Orig3n 2019 Novel Coronavirus (COVID-19) Test | Orig3n, Inc.  | ✓        | ✓ |    |    |   |   | 4/10/20     |
| COVID-19 RT-PCR Test                          | Pathology/Laboratory Medicine Lab of Baptist Hospital Miami                     | ✓        | ✓ |    |    |   |   | 4/13/20     |
| COVID-19 Key                                  | Southwest Regional PCR Laboratory LLC. dba MicroGen DX                          | ✓        | ✓ | ✓  | ✓  |   |   | 4/23/20     |
| SDI SARS-CoV-2 Assay                          | Specialty Diagnostic (SDI) Laboratories   | ✓        | ✓ |    |    |   |   | 4/10/20     |
| Stanford SARS-CoV-2 assay                     | Stanford Health Care Clinical Virology Laboratory                               | ✓        | ✓ | ✓  |    |   |   | 4/8/20      |
| UDX SARS-CoV-2 Molecular Assay                | Ultimate Dx Laboratory  | ✓        | ✓ |    |    |   |   | 4/24/20     |
| UNC Health SARS-CoV-2 real-time RT-PCR test   | University of North Carolina Medical Center                                     | ✓        | ✓ | ✓  |    |   |   | 4/10/20     |



| Test                              | Laboratory  | Specimen |   |    |    |   |   | Date Issued |
|-----------------------------------|---|----------|---|----|----|---|---|-------------|
|                                   |   | N        | O | RS | SP | S | B |             |
| UTHSC/UCH SARS-CoV-2-RT-PCR Assay | UTMG Pathology Laboratory                             | ✓        |   |    |    |   |   | 5/3/20      |
| Viracor SARS-CoV-2 assay          | Viracor Eurofins Clinical Diagnostics                 | ✓        | ✓ | ✓  |    |   |   | 4/6/20      |
| SARS-CoV-2 PCR test               | Yale New Haven Hospital, Clinical Virology Laboratory | ✓        | ✓ | ✓  | ✓  |   |   | 3/31/20     |



## Summary of Non-Authorized COVID-19 Tests

For the most current information on COVID-19 tests that have validated their own tests and have started patient testing and/or distribution, without Emergency Use Authorization (EUA), visit the FDA website: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>

The FDA has not yet reviewed the validation data for these tests and have not yet issued an EUA for the laboratory's or manufacturer's test. The lists of tests is provided by the FDA to provide transparency regarding the notifications submitted to FDA. The FDA does not intend to object to the development and distribution of these tests for a "reasonable period of time" after the manufacturer's self-validation of the test.

If an EUA request is not submitted within a reasonable period of time, or if significant problems are identified with a test and cannot be or have not been addressed in a timely manner, FDA intends to remove the manufacturer and test from this list, would expect the manufacturer to suspend distribution of the test, and may take additional actions as appropriate.

Tests offered prior to or without an EUA are considered to be a high complexity test by default.

### Summary:

Number of laboratories with non-authorized diagnostic tests: 133

Number of laboratories with non-authorized serological tests: 19

Number of manufacturers with non-authorized diagnostic tests: 13

Number of manufacturers with non-authorized serological tests: 191